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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,819	05/26/2000	Vadim Vladimirovich Yuzhakov	7606R	9337

27752 7590 09/22/2004

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CINCINNATI, OH 45224

EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/580,819

Applicant(s)

YUZHAVOV ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 20-24 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-19 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims drawn to an invention nonelected with traverse in Paper No. 11/4/2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, 13-19, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (USPN 6,334,856), and further in view of Kingsford (WO 01/36037).

Allen et al. disclosed a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron (Column 14, lines 18-20) and wherein said length of projections are 50-3000 micron (Column 5, lines 39-58, Figures 1A, 1B, 3G, 4D), the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element and wherein the projections are on the outer surface of said microneedle and extend in a direction from said proximal end of the microneedle.

Kingsford disclosed an hollow elements each exhibit an edged outer contour having at least two sharp projections proximal to an end of the hollow element and wherein the projections are on the outer surface of said microneedle and extend in a direction from said proximal end of the microneedle, (Figures 3A-5, and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Allen et al. with the teachings of Kingsford because Kingsford disclosed a more efficient way to anchor the infusion structure to the organ body (Page 1, lines 20-23).

4. Claims 1-7, 13-19, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (USPN 6,334,856), and further in view of Eicher et al. (WO 97/03718).

Allen et al. disclosed a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron (Column 14, lines 18-20) and wherein said length of projections are 50-3000 micron (Column 5, lines 39-58, Figures 1A, 1B, 3G, 4D), the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element and wherein the projections are on the outer surface of said microneedle and extend in a direction from said proximal end of the microneedle.

Eicher et al. disclosed hollow elements each exhibit an edged outer contour having at least two sharp projections proximal to an end of the hollow element and

wherein the projections are on the outer surface of said microneedle and extend in a direction from said proximal end of the microneedle, (Figures 3d and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Allen et al. with the teachings of Eicher et al. because Eicher et al. disclosed a more efficient way to anchor the infusion structure to the organ body (Page 7).

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose

7. Claims 1-7, 13-19, and 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S.

Patent No. 6,652,478 [Gartstein et al.] in view of U.S. Patent No. 6,334,856 [Allen et al.], because Garstein et al. discloses the same microneedle structure that is claimed in this

application and Allen et al. discloses the separation and length of the microneedles on a base. It would have been obvious to combine the two reference because it is well known in the medical art when using microneedles to make them a certain length and as well as having a certain separation distance so that the microneedle will perform their function appropriately, which is to be able to inject fluid through the upper layer of the skin without affecting the lower layer of the skin and the nerve ends.

#### ***Allowable Subject Matter***

8. Claim 29 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

9. Applicant's arguments filed 12/24/03 have been fully considered but they are not persuasive.

10. The 102 Rejections are Gerstel et al. and Allen et al. are withdrawn because of the amendments and the arguments submitted by the applicant.

#### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 3763


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

  
Matthew DeSanto  
Art Unit 3763  
September 20, 2004

  
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